

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

IN RE PFIZER INC. SECURITIES LITIGATION

04 Civ. 9866 (RO)  
(Electronically filed document)

**DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION  
TO STRIKE CERTAIN EXHIBITS ATTACHED TO THE DECLARATION OF  
GREGORY A. MARKEL AND RELATED PORTIONS OF THE MEMORANDUM OF  
LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS**

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Defendants Pfizer Inc. (“Pfizer”) and Dr. Henry A. McKinnell, Dr. John L. LaMattina, Karen L. Katen, Joseph M. Feczko, M.D. and Gail Cawkwell, M.D. (the “Individual Defendants;” collectively “Defendants”) respectfully submit this brief in opposition to Plaintiffs’ Motion to Strike (the “Motion to Strike” or “MTS”) Certain Exhibits Attached to the Declaration of Gregory A. Markel (“Markel Declaration”) and Related Portions of the Memorandum of Law in Support of Defendants’ Motion to Dismiss (“Defendants’ Opening Brief”) Plaintiffs’ Consolidated Class Action Complaint (the “Complaint”).

### **PRELIMINARY STATEMENT**

Plaintiffs’ Motion to Strike Exhibits 1 and 1a to the Markel Declaration and the related portions of Defendants’ Opening Brief should be denied because these documents can and should be considered by this Court in ruling on Defendants’ Motion to Dismiss.<sup>1</sup>

Bextra was an arthritis pain-relieving drug manufactured by Pfizer. Plaintiffs allege that Defendants misrepresented the cardiovascular safety of Bextra by purportedly concealing the results of the Coronary Artery Bypass Graft Trial 35 (“CABG Trial 35”), a clinical study on Bextra. This Court should consider on Defendants’ Motion to Dismiss the excerpts of the Bextra New Drug Application (“NDA”) and the CABG Trial 35 Final Report (which is part of the Bextra NDA) that are attached to the Markel Declaration as Exhibit 1 because these documents are referenced in the Complaint and are integral to Plaintiffs’ allegations that Defendants made misrepresentations and omissions concerning Bextra. In fact, Plaintiffs’ allegations regarding Bextra hinge virtually exclusively upon the results of the CABG Trial 35. Plaintiffs assert that CABG Trial 35 demonstrated a statistically significant cardiovascular risk associated with Bextra

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<sup>1</sup> Plaintiffs also move to strike Exhibits 2 and 3 to the Markel Declaration, two fact sheets regarding arthritis that are on the website of the Centers for Disease Control and Prevention. Defendants withdraw their request that the Court consider these documents on this motion. As explained in Point I.C, Defendants respectfully request that this Court substitute a new paragraph and supporting documents for the material in Defendants’ Opening Brief for which Exhibits 2 and 3 previously were cited. Plaintiffs do not move to strike exhibits to the Markel Declaration other than Exhibits 1, 1a, 2 and 3. Thus, they concede that the remaining exhibits can be considered by the Court.

and cite portions of the CABG Trial 35 Final Report in their Motion to Strike and Opposition to Defendants' Motion to Dismiss. At the same time, Plaintiffs argue that Defendants should not be allowed to use the Final Report to respond to Plaintiffs' allegations. Plaintiffs cannot have it both ways.

This Court should also consider on Defendants' Motion to Dismiss the definition of the term statistical significance from the Primer on Statistical Significance and P Values published by the American College of Physicians in Effective Clinical Practice, a medical journal, which is attached to the Markel Declaration as Exhibit 1a ("Statistical Significance Primer"). The Court may take judicial notice of the definition in the Statistical Significance Primer because it is not subject to reasonable dispute that if the "probability that the observed result [of a study] is due to chance" is "less than 5%, researchers typically assert that the findings are 'statistically significant.'"<sup>2</sup>

Defendants cited Exhibit 1a to assist the Court because the document explains the term statistical significance. Although the term is used in many of the key cases cited in Defendants' Opening Brief, it is not explained in those cases. Contrary to Plaintiffs' assertion, the meaning of statistical significance does not create an issue of fact such that the Court cannot address statistical significance on the Motion to Dismiss. In fact, in the Carter-Wallace decisions,<sup>3</sup> the Second Circuit established the statistical significance standard applicable to this case in its review of motions to dismiss, and affirmed the dismissal of Section 10(b) claims. In Carter-Wallace II, the Second Circuit affirmed the dismissal of a Section 10(b) claim on a motion to dismiss on the ground that the defendant drug manufacturer was not reckless in failing to disclose reports of adverse events experienced by patients taking its drug that did not demonstrate a statistically significant causal link between the drug and the adverse events.

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<sup>2</sup> Markel Decl. Ex. 1a (American College of Physicians, Primer on Statistical Significance and P Values, available at <http://www.acponline.org/journals/ecp/julaug01/primer.htm>).

<sup>3</sup> In re Carter-Wallace, Inc. Sec. Litig., 150 F.3d 153 (2d Cir. 1998) ("Carter-Wallace I") and In re Carter-Wallace, Inc. Sec. Litig., 220 F.3d 36 (2d Cir. 2000) ("Carter-Wallace II"; collectively, "Carter-Wallace").



Similarly, this Court can and should consider Exhibit 1a and dismiss Plaintiffs' claims because Plaintiffs do not plead facts to show that the purportedly undisclosed results of the Alzheimer's 001 study and CLASS Study regarding Celebrex and the CABG Trial 35 regarding Bextra demonstrated a statistically significant causal link between Bextra and Celebrex and cardiovascular risk.

The description of statistical significance employed in the Statistical Significance Primer can be considered on this motion because it is an accepted test, which, as the Primer describes, is "typically" used by researchers. Markel Ex. 1a at 2. Plaintiffs do not dispute that statistical significance refers to the probability that a result is due to chance, nor do they contest the reliability of the source of this definition. While they claim that the measure of statistical significance can be defined differently than 5%, they do not claim that the definition does not set forth the typical test. Indeed, the FDA uses the same measure of statistical significance. The FDA's Guidance for Industry, Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products ("FDA Guidance for Industry") expressly refers to 5% as the "conventional level[ ] of statistical significance." Supplemental Declaration of Gregory A. Markel ("Supp. Markel Decl.") Ex. 45 at 5.<sup>4</sup> The 5% threshold for statistical significance was also used in each of the studies on which Plaintiffs' allegations rely: CABG Trial 35 regarding Bextra, the Alzheimer's 001 Study of Celebrex, and the CLASS Study regarding Celebrex. Plaintiffs do not and cannot contend that the standard applied in these studies is not widely accepted. Because,

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<sup>4</sup> This document is publicly available at <http://www.fda.gov/cder/guidance/1397fn1.pdf>. Defendants respectfully request that the FDA Guidance for Industry be considered on Defendants' Motion to Dismiss. It is appropriate for this Court to take judicial notice of the FDA's Guidance for Industry because it is an FDA report available on the FDA's website. Courts regularly take judicial notice of such documents. See In re Wellbutrin Sr/Zyban Antitrust Litig., 281 F. Supp. 2d 751, 754 n.2 (E.D. Pa. 2003) (taking judicial notice of FDA report posted on the FDA's official website); United States v. Bioport Corp., 270 F. Supp. 2d 968, 972 (W.D. Mich. 2003) (court can take judicial notice of government documents on a motion to dismiss, including those available from reliable sources on the internet), aff'd, 388 F.3d 209 (6th Cir. 2004), cert. denied, 544 U.S. 949 (2005). Indeed, Defendants attached several documents from the FDA's website to the Markel Declaration submitted in support of their Motion to Dismiss, none of which Plaintiffs have contested on this motion. See Markel Decl. Exs. 5, 8, 9, 12, 13, 14, 16, 17, 18, 19, 26, 27, 28, 29a, 30, 31.

under Carter-Wallace, the Court must evaluate statistical significance, it is unquestionable that the Court may review a widely accepted definition of that term and deny Plaintiffs' motion to strike Exhibit 1a.<sup>5</sup>

### **STATEMENT OF FACTS**

This is a putative class action. Cplt. at 1. Defendants are Pfizer<sup>6</sup> and certain of its officers. Id. ¶ 1. Plaintiffs assert claims against Defendants under Sections 10(b), 18, 20A and 20(a) of the Securities and Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, as well as for common law fraud and violations of unspecified state securities laws. Id. ¶¶ 297-363. Plaintiffs base these claims on allegations that Defendants made misrepresentations regarding the cardiovascular safety of Celebrex and Bextra during the Class Period. To support their allegations regarding Bextra, Plaintiffs rely virtually exclusively on a single clinical study, CABG Trial 35. Plaintiffs allege that Defendants concealed CABG Trial 35 from the public and that the results of the study showed that Bextra posed cardiovascular risks. Id. ¶¶ 118, 214; see Def. Br. at 42-46. On January 16, 2001, Pfizer submitted an NDA for Bextra, which included the results of CABG Trial 35, to the FDA. Markel Decl. Ex. 1. The results of CABG Trial 35 were published in the Journal of Thoracic and Cardiovascular Surgery in June, 2003. See Markel Decl. Ex. 29.

On May 5, 2006, Defendants filed a Motion to Dismiss Plaintiffs' Complaint as well as the Markel Declaration, which attached certain documents that may properly be considered by the Court in support of Defendants' Motion. On June 19, 2006, Plaintiffs filed a brief in Opposition to Defendants' Motion to Dismiss as well as a Motion to Strike four of the exhibits to the Markel Declaration and the references to those exhibits in Defendants' Motion to Dismiss.

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<sup>5</sup> This brief focuses on why this Court should consider Exhibits 1 and 1a on Defendants' Motion to Dismiss. Because Plaintiffs' Motion to Strike makes factual contentions and legal arguments relevant to Defendants' Motion to Dismiss, Defendants incorporate by reference their Opening and Reply Briefs in support of their Motion to Dismiss rather than repeat those arguments here.

<sup>6</sup> In this brief, as in the Motion to Dismiss, Defendants refer to Pfizer throughout rather than to its predecessor companies regardless of the time period at issue.

Exhibit 1 to the Markel Declaration contains excerpts of the Bextra NDA, including portions of the CABG Trial 35 Final Report. Plaintiffs reference CABG Trial 35 over thirty times in the Complaint and describe various details of CABG Trial 35, including the number of participants in the study, the adverse events reported, and the study's methodology and results. Cplt. ¶¶ 108-12, 118-19. Plaintiffs claim that Defendants' statements about the cardiovascular safety of Bextra were false and misleading in light of the results of CABG Trial 35. See id. ¶¶ 108-12, 118-19, 186-87, 191-93, 213-14, 216-18, 228-31, 250-51. CABG Trial 35 concluded, however, that there was no evidence that parecoxib sodium/Bextra "presents an increased risk for global cardiovascular events." Markel Decl. Ex. 1 at 125 (CABG Trial 35). The CABG Trial 35 Final Report also found that "while parecoxib/[Bextra] was associated with numerically, but statistically nonsignificant, higher rates of [cerebrovascular accidents] and major infections in this trial, the results of this study do not conclusively determine the relationship between these events and treatment with parecoxib/[Bextra]." Id. at 130-31.

Plaintiffs also reference the Bextra NDA in the Complaint. They note that the Bextra NDA was submitted to the FDA in April 2001 and that it sought approval for the use of Bextra in treating symptoms of osteoarthritis, rheumatoid arthritis and certain types of pain. Cplt. ¶¶ 60, 106. Defendants submitted the relevant portions of the Bextra NDA with their motion rather than the full document because the Bextra NDA is voluminous. In addition to including a copy of the CABG Trial 35 Final Report, the Bextra NDA also includes over 60 other studies Pfizer submitted to the FDA as part of the Bextra NDA. These studies found that the incidence of adverse cardiovascular events was "not significantly different than seen with placebo or NSAID Treatment." Markel Decl. Ex. 1 at 55 of Summary of Benefits and Risks (Bextra NDA). The Bextra NDA also contains Pfizer's draft proposed label for Bextra, which cautioned that post-CABG patients who are elderly or who have a history of cerebrovascular disease may have an increased risk of adverse events. Id. at 19 of Pfizer Draft US Labeling for [Bextra] tablets, Jan. 4, 2001.

Exhibit 1a to the Markel Declaration, the Statistical Significance Primer, defines the term

statistically significant. It provides that if the “probability that the observed result [of a study] is due to chance” is “less than 5%, researchers typically assert that the findings are ‘statistically significant.’”<sup>7</sup>

### **ARGUMENT**

#### **PLAINTIFFS’ MOTION TO STRIKE SHOULD BE DENIED BECAUSE EACH CONTESTED EXHIBIT MAY PROPERLY BE CONSIDERED ON A MOTION TO DISMISS.**

Under Second Circuit law, in ruling on a motion to dismiss, a court may consider “any statements or documents incorporated in [the complaint] by reference,’ and any document not incorporated but that is, nevertheless, ‘integral’ to the complaint because the complaint ‘relies heavily upon its terms and effect.’” Yung v. Lee, 432 F.3d 142, 146 (2d Cir. 2005) (citation omitted).<sup>8</sup> A court may consider a document of which Plaintiffs have knowledge and upon which they rely, even if Plaintiffs do not personally possess the document, Cortec Indus. Inc. v. Sum Holding L.P., 949 F.2d 42, 48 (2d Cir. 1991) (the court may consider “documents plaintiffs had either in [their] possession or had knowledge of and upon which they relied in bringing suit.”) (emphasis added).<sup>9</sup> In addition, a court may consider “matters of which judicial notice

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<sup>7</sup> Markel Decl. Ex. 1a; see also Def. Br. at 2 n.1.

<sup>8</sup> Indeed, Plaintiffs concede that courts may take judicial notice of a variety of documents outside of the complaint when considering a motion to dismiss. See MTS at 15-16, n. 12, 13, 14. Moreover, Plaintiffs’ cases confirm the well-settled principle that courts can consider documents that are integral to the plaintiffs’ claims even if they are not appended to the complaint or incorporated by reference. See Harris v. Ivax Corp., 182 F.3d 799, 802, n. 2 (11th Cir. 1999) (district court properly considered full text of press release that was appended to the defendants’ motion and “central to the complaint”); Thomas v. Westchester County Health Care Corp., 232 F. Supp. 2d 273, 275-76 (S.D.N.Y. 2002) (transcript and report of employee’s disciplinary hearing may be considered, despite plaintiff’s failure to attach them to the complaint, because the documents were integral to plaintiff’s claims that the disciplinary proceedings constituted discrimination).

<sup>9</sup> Plaintiffs’ cases are not to the contrary. See MTS at 9-10. In Friedl v. City of New York, 210 F.3d 79, 83 (2d Cir. 2000), the plaintiff attempted to rely on factual contentions in a declaration, not documents that were integral to or relied upon in the complaint or capable of judicial notice. In Newman & Schwartz v. Asplundh Tree Expert Co., 102 F.3d 660, 661 (2d Cir. 1996), the court stated that the district court erred in considering a 16 paragraph evidentiary affirmation that the defendant submitted in support of its motion to dismiss, which attached “copies of correspondence to which no reference had been made in the complaint.” In Kopec v. Coughlin, 922 F.2d 152, 155 (2d Cir. 1991), a civil rights action brought by a

may be taken” pursuant to Federal Rule of Evidence 201. Brass v. American Film Techs., Inc., 987 F.2d 142, 150 (2d Cir. 1993). Rule 201(b) provides that “[a] judicially noticed fact must be one not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot be reasonably questioned.” Rule 201(f) provides that “[j]udicial notice may be taken at any stage of the proceeding.”

As shown below, Plaintiffs’ Motion to Strike the Bextra NDA/ CABG Trial 35 and Statistical Significance Primer should be denied because these documents can be considered on Defendants’ Motion to Dismiss pursuant to these legal principles. Considering these documents in connection with Defendant’s Motion to Dismiss is entirely appropriate and would not convert Defendants’ Motion to Dismiss into a motion for summary judgment.<sup>10</sup>

**A. This Court Should Consider the Excerpts of the Bextra NDA and the CABG Trial 35 Results**

The Court may consider Exhibit 1, which contains the results of the CABG Trial 35 Study and other portions of the Bextra NDA, because these documents are referenced in the Complaint and are integral to Plaintiffs’ claims regarding Bextra. See Cortec, 949 F.2d at 47-48. Plaintiffs’ assertion that the Bextra NDA and CABG Trial 35 results are not referenced in the Complaint, see MTS at 15, is incorrect. Plaintiffs refer to CABG Trial 35 throughout the

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prisoner, the court found that the district court improperly considered factual matter contained in affidavits and other exhibits in deciding a motion to dismiss.

<sup>10</sup> It would be inappropriate to convert the motion to dismiss to one for summary judgment, since all of the documents attached to the Markel Declaration can be considered on a motion to dismiss pursuant to the legal principles cited herein. See also Def. Br. at 2 n.3. To the extent the Court concludes that the challenged exhibits cannot be considered on this motion, the Court should simply disregard the documents and the material for which they are cited, thereby rendering moot the motion to strike: “a trial court should not transform a 12(b)(6) motion into a summary judgment motion where, as here, the motion has been filed in lieu of an answer, and the parties have neither completed discovery nor formally requested that the motion be converted.” Giant Group, Ltd. v. Sands, 142 F. Supp. 2d 503, 506 (S.D.N.Y. 2001); see also In re Elan Corp. Sec. Litig., No. 02Civ.865 (RMB)(FM), 2004 WL 1305845, at \*28 (S.D.N.Y. May 18, 2004) (plaintiffs’ motion to strike certain exhibits was rendered moot where court did not consider the exhibits). As Plaintiffs acknowledge, discovery in this action is stayed pending this Court’s ruling on Defendants’ Motion to Dismiss under the Private Securities Litigation Reform Act, 15 U.S.C. § 78u-4(b). MTS at 19-20.

Complaint and also describe the Bextra NDA. Cplt. ¶¶ 60, 106, 108-12, 118-19, 186-87, 191-93, 213-14, 216-18, 228-31, 250-51. Because these documents are referenced in the Complaint, they are properly considered on Defendants' Motion to Dismiss. See Cortec, 949 F.2d at 47; Matusovsky v. Merrill Lynch, 186 F. Supp. 2d 397, 400 (S.D.N.Y. 2002) (in ruling on motion to dismiss, court considered document "explicitly referenced" in complaint).<sup>11</sup>

It is clear that Plaintiffs had knowledge of the Bextra NDA and CABG Trial 35 in preparing the Complaint and that these documents are integral to Plaintiffs' claims. The centerpiece of Plaintiffs' claim that Defendants made false and misleading statements regarding the cardiovascular safety of Bextra is that Defendants purportedly concealed the results of CABG Trial 35. See, e.g., Cplt. ¶¶ 110-11, 118-19, 178, 184, 186-87, 228-31, 247, 250-51. In fact, CABG Trial 35 is mentioned over thirty times in the Complaint. The Complaint describes various details of the CABG Trial 35, including the number of participants in the study, the adverse events reported, and the study's methodology. See id. ¶¶ 108-12, 118-19.

The Complaint also references the Bextra NDA. Plaintiffs allege that the Bextra NDA was submitted to the FDA in April 2001 and that it sought approval for the use of Bextra in

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<sup>11</sup> Although Plaintiffs note that the Second Circuit in Chambers held that the district court had incorrectly considered certain collective bargaining codes in ruling on the motion to dismiss because they were not referenced in the complaint or integral to the claims (MTS at 12), Plaintiffs conveniently fail to mention that the court found that the district court had properly considered contracts that were integral to the complaint. See Chambers v. Time Warner, Inc., 282 F.3d 147, 154 (2d Cir. 2002). Thus, Chambers supports the consideration of the excerpts of the Bextra NDA and CABG Trial 35 because they are referenced in the Complaint and integral to Plaintiffs' claims. The other cases that Plaintiffs cite are distinguishable from this case. Official Committee of the Unsecured Creditors of Color Tile, Inc. v. Coopers & Lybrand, LLP (MTS at 2) differs from this case because there, the Second Circuit noted that it could not consider testimony from a deposition taken after certain claims were sustained in determining whether other claims should have been dismissed under Rule 12(b)(6). 322 F.3d 147, 160 n.7 (2d Cir. 2003). Likewise, SEC v. Downe, No. 92 Civ 4092 (PKL), 1993 WL 22126 at \*14 n.3 (S.D.N.Y. Jan. 26, 1993), In re Cree, Inc. Sec. Litig., 333 F. Supp. 2d 461, 470-71 (M.D.N.C. 2004), and In re OPUS 360 Corp. Sec. Litig., No. 01 Civ. 2938 (JGK) (JCF), 2002 WL 31190157, at \*1 n.3 (S.D.N.Y. Oct. 2, 2002) are distinguishable because the documents at issue in those cases were not integral to the complaints. See MTS at 10, 15. In addition, Adams v. Crystal City Marriott Hotel, No. 02 Civ. 10258 PKL, 2004 WL 744489, at \*2-3 (S.D.N.Y. Apr. 6, 2004) differs from this case because in that case, the court declined to consider a certification that plaintiffs' counsel filed after the motion to dismiss was fully submitted that "resemble[d] a declaration or affidavit."

treating symptoms of osteoarthritis, rheumatoid arthritis and certain types of pain. Cplt. ¶¶ 60, 106. Further, Plaintiffs purport to have “knowledge of” the contents of the Bextra NDA because they describe the conditions for which it sought approval. Id. ¶¶ 106-119. Plaintiffs’ assertion that the Court has the power to strike documents outside the scope of the Complaint (MTS at 10), is irrelevant where, as here, the documents are relied upon and integral to the Complaint.<sup>12</sup> The allegations in the Complaint demonstrate that Plaintiffs had notice of the contents of the challenged exhibits. See Cortec, 949 F.2d at 48. Plaintiffs do not cite a single case in which a court refused to consider documents critical to a plaintiff’s claims that were referenced throughout the Complaint.

Contrary to Plaintiffs’ assertion, the fact that Plaintiffs do not possess a copy of the full Bextra NDA and the CABG Trial 35 Final Report because these documents are not publicly available does not require striking them. See MTS at 13. In the Second Circuit, a plaintiff’s possession of the document is not a prerequisite for judicial consideration. Rather, the Court may consider a document in ruling on a motion to dismiss provided that a plaintiff has knowledge of the document and relied on it in its complaint. See Cortec, 949 F.2d at 48 (district court could consider stock purchase agreement, offering memorandum, and warrant attached to motion to dismiss even though these documents were not publicly available and were not referenced in the complaint because they were integral to the allegations). As explained above, Plaintiffs clearly knew of and relied upon CABG Trial 35 and the Bextra NDA. Although the CABG Trial 35 Final Report itself is not publicly available, its results are publicly available. They were published in the Journal of Thoracic and Cardiovascular Surgery in June, 2003.

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<sup>12</sup> See Cortec, 949 F.2d at 48 (considering “documents plaintiffs had either in [their] possession or had knowledge of and upon which they relied in bringing suit”); Nappier v. Pricewaterhouse Coopers LLP, 227 F. Supp. 2d 263, 270 n.1 (D.N.J. 2002) (in ruling on motion to dismiss, court considered documents allegedly created or reviewed by defendant accounting firm in connection with an audit where the documents were referenced in the complaint and provided the basis for the plaintiffs’ scienter allegations); Sazerac Co. v. Falk, 861 F. Supp. 253, 257 (S.D.N.Y. 1994) (considering a share purchase agreement on a motion to dismiss even though agreement was not attached to complaint because plaintiff’s claim was based on the agreement).



Markel Decl. Ex. 29. The fact that Plaintiffs have notice of the results is demonstrated by the many references to those results in the Complaint.<sup>13</sup> Thus, it is appropriate for the Court to consider these documents in ruling on Defendants' Motion to Dismiss.

In contrast to Plaintiffs' erroneous assertion, Defendants are not requesting that the Court consider the excerpts of the Bextra NDA and CABG Trial 35 Final Report for the truth of those excerpts, but rather for what these documents stated and what was disclosed to the FDA. See MTS at 11-12, 18. Courts routinely consider documents integral to and relied upon in the Complaint to show what, when and to whom information was communicated.<sup>14</sup> Further, where, as here, documents contradict the allegations of the complaint, "the documents control and [the] Court need not accept as true allegations in the . . . complaint." See Rapoport v. Asia Elecs. Holding Co., 88 F. Supp. 2d 179, 184 (S.D.N.Y. 2000) (dismissing claims under Sections 11, 12(a)(2) and 15 of the Securities Act because the newspaper article and prospectus that the plaintiffs relied upon, but did not attach to their complaint, contradicted their allegations); see also In re: Bayer AG Sec. Litig., 03 Civ. 1546 (WHP), 2004 U.S. Dist. LEXIS 19593, at \*31 (S.D.N.Y. Sept. 30, 2004) (court "need not accept as true an allegation that is contradicted by documents on which the complaint relies"); Sazerac, 861 F. Supp. 2d at 251 (where instruments supplied by defendants in support of motion to dismiss contradict complaint's allegations, court need not accept as true those allegations).

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<sup>13</sup> Plaintiffs' argument that certain cases Defendants cited in their Opening Brief (see Def. Br. at 2 n.3) do not support the consideration of the disputed exhibits is misguided. MTS at 16-18. Defendants cited Kramer, Wellbutrin and Chan as support for their argument that this Court should consider documents attached to the Markel Declaration that Plaintiffs have not moved to strike.

<sup>14</sup> See, e.g., Bryant v. Avado Brands, Inc., 187 F.3d 1271, 1278 (11th Cir. 1999) (district court erred in striking certain documents attached to defendants' motion to dismiss because it was authorized to consider them "for the purpose of determining what statements the documents contain"); Lovelace v. Software Spectrum Inc., 78 F.3d 1015, 1119 (5th Cir. 1996) (affirming dismissal of Section 10(b) claim where SEC filing disclosed the information that the plaintiffs claimed was omitted and therefore refuted the plaintiffs' claim); Kramer v. Time Warner Inc., 937 F.2d 767, 774 (2d Cir. 1991) (SEC filings may be considered "to determine what the documents stated"); In re Bristol-Myers Squibb Sec. Litig., 312 F. Supp. 2d 549, 566 (S.D.N.Y. 2004) (finding that documents attached by the defendants contradicted allegations in complaint that sales were "consignment sales").



For example, in Bayer, the defendant attached the purportedly undisclosed clinical study at issue as an exhibit to an affidavit in support of the defendant's motion to dismiss where the plaintiffs had alleged that the study showed that the defendant's drug was unsafe. 2004 U.S. Dist. LEXIS 19593, at \*\*9, 31-32. The Bayer court considered the text of the study on a motion to dismiss. It found that, contrary to the plaintiff's allegations, the study "concluded that Baycol 'had a good tolerability and safety profile' a fact the Complaint overlooks," and therefore, the study "was consistent with defendants' statements." Id. at \*31. Accordingly, the court concluded that the defendant was not required to disclose the study and could not be held liable on the basis of the study's results. See id.<sup>15</sup> Similarly, this Court can and should consider on Defendants' Motion to Dismiss that the excerpts of the CABG Trial 35 Final Report and Bextra NDA contradict Plaintiffs' allegations that CABG Trial 35 demonstrated a cardiovascular risk associated with Bextra that Defendants had a duty to disclose.

The Eleventh Circuit's decision in Oxford Asset Management, Ltd. v. Jaharis, 297 F.3d 1182, 1188 (11th Cir. 2002) is another example. In Oxford, the plaintiff alleged that the defendants' statements in a prospectus that the drug at issue could increase HDL ("good") cholesterol by 22% to 32% were false and misleading. The Eleventh Circuit found that the district court, in ruling on the motion to dismiss, did not err in considering a document submitted by defendants that referred to a clinical study that "stated that [the drug at issue] could increase HDL cholesterol by 32%." Id. at 1188, 1192-1193. The court determined that plaintiffs failed to allege sufficient facts to show that defendants' statement that the drug could increase HDL cholesterol by 32% was false. See id. at 1192-1193.

Like the study results at issue in Bayer and Oxford, the results of the CABG Trial 35 contradict Plaintiffs' allegations because they show that the study did not reveal a statistically significant link between Bextra and cardiovascular events. CABG Trial 35 concluded that there

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<sup>15</sup> With respect to a different study, the Bayer court relied on a statement in the study to conclude that it was misleading for the company to withhold the study after the Bayer executives came to a consensus that the brand was at risk. See Bayer, 2004 U.S. Dist. LEXIS 19593, at \*\*13-14, 29.

was no evidence that parecoxib sodium/Bextra “presents an increased risk for global cardiovascular events.” Markel Decl. Ex. 1 at 125 (CABG Trial 35). The Final Report of the study also found that “while parecoxib/[Bextra] was associated with numerically, but statistically nonsignificant, higher rates of [cerebrovascular accidents] and major infections in this trial, the results of this study do not conclusively determine the relationship between these events and treatment with parecoxib/[Bextra].” Id. at 130-31.

Similarly, the NDA also readily refutes many of Plaintiffs’ allegations about CABG Trial 35 and Bextra. For example, it contradicts Plaintiffs’ allegation that Defendants concealed the results of CABG Trial 35, because it contains the results of CABG Trial 35. Id. ¶¶ 118, 214. The Bextra NDA also includes Pfizer’s draft proposed label for Bextra, which cautioned that post-CABG patients who are elderly or who have a history of cerebrovascular disease may have an increased risk of adverse events, including cardiovascular events. Markel Decl. Ex. 1 at 125 (CABG Trial 35); Markel Decl. Ex. 14 at 1 (Bextra Approval Package). The inclusion of the draft label with this disclosure in the NDA further shows that Defendants did not conceal the results of CABG Trial 35. The Bextra NDA also contradicts Plaintiffs’ allegation that Bextra posed an increased cardiovascular risk because it described the results of over 60 clinical trials, including CABG Trial 35, and observed that the incidence of adverse cardiovascular events in these studies was “not significantly different than seen with Placebo or NSAID treatment.” Markel Decl. Ex. 1 at 55 of Sum. of Benefits and Risks (Bextra NDA); id. at 125 (CABG Trial 35).

As in Bayer and Oxford, in which the courts considered the conclusions of clinical studies on motions to dismiss, this Court should consider the CABG Trial 35 results, which plainly contradict Plaintiffs’ allegations that Defendants concealed the results of CABG Trial 35 and that the study showed a statistically significant causal connection between Bextra and cardiovascular events. See Bayer, 2004 U.S. Dist. LEXIS 19593, at \*31 (noting that “the court need not accept as true an allegation that is contradicted by documents on which the complaint relies”) (quoting Bristol-Myers, 312 F. Supp. 2d at 555). Contrary to Plaintiffs’ assertions,

CABG Trial 35 did not demonstrate a statistically significant causal connection between Bextra and cardiovascular events. Rather, the CABG Trial 35 results included in the NDA concluded that there was no evidence that parecoxib sodium/Bextra “presents an increased risk for global cardiovascular events.” Markel Decl. Ex. 1 at 125 (CABG Trial 35). Plaintiffs do not cite a single case in which a court declined to consider the report of a clinical study or new drug application at issue in the case.<sup>16</sup>

Plaintiffs’ argument that it would be “unfair” to Plaintiffs for the Court to consider the excerpts from the Bextra NDA / CABG Trial 35 Final Report because Plaintiffs have not had an opportunity to review the entire document also fails. See MTS at 13. In their Motion to Strike and Opposition to Defendants’ Motion to Dismiss, Plaintiffs contend (albeit erroneously) that these very excerpts support their Bextra claims. See id. at 3, 4, 13 n.10; Opp. at 37 n.30. Moreover, there is nothing wrong with the Court’s consideration of excerpts of a document. See, e.g., In re: Vicuron Pharms., Inc. Sec. Litig., No. Civ.A. 04-2627, 2005 WL 2989674, at \*3 (E.D.Pa. July 1, 2005) (denying the plaintiffs’ motion to strike “excerpts [of texts] discussing [a] technical term,” and excerpts of SEC filings, which defendants submitted in support of their motion to dismiss). Defendants note that the Bextra NDA consists of thousands of pages, including 60 clinical studies. Moreover, each subsection of the Bextra NDA that Defendants cite or quote in the Opening and Reply Briefs is included in its entirety as part of Exhibit 1.<sup>17</sup>

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<sup>16</sup> Indeed, it is in the interest of judicial economy for the Court to consider the excerpts of the CABG Trial 35 Final Report and Bextra NDA in ruling on Defendants’ Motion to Dismiss because the excerpts demonstrate the insufficiency of Plaintiffs’ claims with respect to Bextra. It would be a waste of judicial resources and result in undue expense to the parties if the Court declined to consider the excerpts of the Bextra NDA/CABG Trial 35 Final Report in conjunction with Defendants’ Motion to Dismiss because they demonstrate that Plaintiffs’ claims with respect to Bextra should be dismissed.

<sup>17</sup> Since Defendants provided the relevant subsections of the NDA in their entirety to Plaintiffs, Plaintiffs’ reliance on Federal Rule of Evidence 106 for their assertion that it is unfair that Defendants provided excerpts of the Bextra NDA and CABG Trial 35 report as opposed to complete documents (MTS at 13) is misplaced. Under this rule, Defendants had no obligation to provide the portions of these documents that are irrelevant to Plaintiffs’ claims since no unfairness can result. Cf. United States v. Jackson, 180 F.3d 55, 73 (2d Cir. 1999) (“The completeness doctrine does not [ ] require the admission of portions of a statement that are neither explanatory nor relevant to the admitted passages.”).

**B. The Court May Take Judicial Notice of the Definition of Statistical Significance**

It is proper for the court to take judicial notice of the definition of statistical significance contained in the Statistical Significance Primer because Plaintiffs do not contest the reliability of the source or the definition. Defendants submitted the Statistical Significance Primer to provide the Court with a definition of statistical significance, a term used in the Second Circuit's decisions in Carter-Wallace, which established the standard for disclosing adverse events occurring during the use of a drug and for pleading scienter which respect to alleged failures to disclose such adverse events. See In re Carter-Wallace I, 150 F.3d at 157; Carter-Wallace II, 220 F.3d at 40. Plaintiffs' argument that this document should not be considered because it was not incorporated in the Complaint or relied upon by Plaintiffs and is being offered for its truth fails because the document is an appropriate subject for judicial notice. MTS at 14, 18. In ruling on a motion to dismiss, the Court may consider documents which are capable of judicial notice under Federal Rule of Evidence 201. See Brass, 987 F.2d at 150. Under Rule 201(b), judicially noticeable facts are those not subject to reasonable dispute in that they are either "generally known" or "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned."

Further, as a general matter, courts regularly take judicial notice of definitions and other material contained in standard reference works.<sup>18</sup> Plaintiffs here fail to show that the Primer's definition of statistical significance is not generally accepted. The description of statistical significance employed in the Statistical Significance Primer can be considered on this motion

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<sup>18</sup> See Nix v. Hedden, 149 U.S. 304, 307 (1893) (taking judicial notice of dictionary definition, "not as evidence, but only as aids to the memory and understanding of the court"); Vicuron, 2005 WL 2989674, at \*3 (taking judicial notice of two "excerpts discussing the technical term 'volume of distribution' from two [medical] reference materials . . . [where] Plaintiffs do not dispute the accuracy of the reference texts or the definitional information"); Savings Bank Life Ins. Co. of Massachusetts v. SBLI USA Mut. Life Ins. Co., No. CIV.A.00-3255, 2000 WL 1758818, at \*12 (E.D. Pa. Nov. 29, 2000) (finding that the Court may take judicial notice of definitions); Azoplate Corp. v. Silverlith, Inc., 367 F. Supp. 711, 731 (D. Del. 1973) (taking judicial notice of definition of term in standard chemical dictionaries.); Owens-Illinois Glass Co. v. American Coastal Lines, Inc., 222 F. Supp. 923, 927 (S.D.N.Y. 1963) (taking judicial notice of material in standard financial book of reference).

because it is “typically” used by researchers. Markel Ex. 1a at 2. In fact, the three studies at issue in this case (CLASS Study, the Alzheimer’s 001 Study and the CABG Trial 35) all used a 5 % threshold value for evaluating statistical significance.<sup>19</sup> Plaintiffs do not assert that the threshold used is not the conventional measure for statistical significance. Nor can they. The FDA has recognized in its reference guide for applicants seeking the approval of drugs that 5% is the “conventional level[] of statistical significance.” See Supp. Markel Decl. Ex. 45 at 5 & n.5 (Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products, dated May 1998, publicly available at <http://www.fda.gov/cder/guidance/1397fnl.pdf>). Thus, Plaintiffs fail to show that the 5% measure of statistical significance described in Exhibit 1a should not be considered.

Nor do Plaintiffs dispute the reliability of the source of the definition. The Statistical Significance Primer is available on the official website of the American College of Physicians, a well-known medical association, and was published in a medical journal.<sup>20</sup> Moreover, courts regularly take judicial notice of published material that relates to the subject matter of the action. See Bioport, 270 F. Supp. 2d at 972 (taking judicial notice of a journal article that concerned subject matter of case because the source of the information was not subject to reasonable dispute). Therefore, this Court should consider the definition of statistical significance in deciding Defendants’ Motion to Dismiss.

Contrary to Plaintiffs’ contention (MTS at 14), the meaning of statistical significance does not raise a fact issue that cannot be decided on a motion to dismiss. If it did create a fact issue, the Second Circuit could not have affirmed the district court’s dismissal of the Section 10(b) claims on motions to dismiss in the Carter-Wallace cases. In Carter-Wallace II, the court

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<sup>19</sup> See Markel Decl. Ex. 33 at 1249 (JAMA article) (stating that the CLASS study used a “2-sided .05 significance level”); Markel Decl. Ex. 10 at 2 (Alzheimer’s 001 Clinical Study Synopsis) (“All statistical tests were two-sided of size  $\alpha=0.05$ .”); Markel Decl. Ex. 1 at 6 (CABG Trial 35) (indicating that CABG Trial 35 used the  $p<0.05$  threshold for statistical significance).

<sup>20</sup> Plaintiffs do not contest the other medical journal articles that Defendants attached to the Markel Declaration. See Markel Decl. Exs. 4, 15, 29, 33.

held that defendant's alleged failure to disclose reports of adverse events experienced by patients taking its drug was not reckless where those events did not demonstrate a statistically significant causal link between the drug and the adverse event. 220 F.3d at 40. Similarly, the purportedly undisclosed results of the Alzheimer's 001 Study and CLASS Study regarding Celebrex and the CABG Trial 35 regarding Bextra did not demonstrate a causal link between Bextra and Celebrex and a statistically significant cardiovascular risk such that it was reckless not to disclose the results. Thus, this Court can and should dismiss Plaintiffs' Section 10(b) claim at this stage of the litigation.

**C. Defendants Request that this Court Consider Substitute Material Regarding Arthritis**

Defendants withdraw their request that the Court consider the informational sheets containing background information about arthritis attached as Exhibits 2 and 3 to the Markel Declaration. Instead, Defendants respectfully request that the Court replace the paragraph in the Opening Brief citing these documents (Def. Br. at p. 3) with a new, similar paragraph:

Celebrex and Bextra are both non-steroidal anti-inflammatory drugs like the popular pain relievers ibuprofen (Advil or Motrin) and naproxen (Aleve) ("NSAIDs") which belong to a class of drugs known as COX-2 inhibitors. NSAIDs are designed to reduce pain and inflammation. Cplt. ¶ 42. Celebrex, which remains on the market, treats pain that would otherwise be debilitating for many arthritis sufferers. In fact, arthritis is the number one cause of disability in the United States, restricting the regular activities of over 7 million Americans. Supp. Markel Decl. Ex. 48 (2/22/00 Joint Pfizer/Pharmacia Press Release) (quoted in Cplt. ¶ 161). Millions of Americans suffer from some form of arthritis. *Id.* Among the various forms of arthritis, osteoarthritis ("OA"), which is characterized by the degeneration of joint cartilage and adjacent bone, is a chronic disorder affecting 21 million American adults. Supp. Markel Decl. Ex. 49 (11/19/01 Joint Pfizer/Pharmacia Press Release) (cited in Cplt. ¶ 178). Rheumatoid arthritis ("RA") affects more than 2.1 million Americans and is an autoimmune disease afflicting joint lining, cartilage and bones. *Id.* It causes inflammation and joint damage. *See* Cplt. ¶ 50.

Because arthritis causes chronic pain, sufferers seek drugs that reduce pain and inflammation for relief. See id. ¶ 42.

The new paragraph cites two Pfizer press releases in addition to the Complaint. It is appropriate for the Court to consider material cited from these press releases because Plaintiffs quote the press releases in the Complaint.<sup>21</sup>

### **CONCLUSION**

For the foregoing reasons, Defendants respectfully request that Plaintiffs' Motion to Strike be denied.

Dated: New York, New York  
August 2, 2006

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<sup>21</sup> See San Leandro Emergency Med. Group Profit Sharing Plan v. Philip Morris Cos., 75 F.3d 801, 808-09 (2d Cir. 1996) (trial court properly considered press releases, newspaper and magazine articles, annual reports, and wire service releases that were partially quoted from or relied on in the complaint); Rapoport, 88 F. Supp. 2d at 184 (considering newspaper article relied on and quoted in complaint). In addition, the Court may take judicial notice of the facts about arthritis contained in these documents because they are well-known medical facts and statistics. See Parker v. Brown, 317 U.S. 341, 363 & n.9 (1943) (taking judicial notice of statistics concerning raisin production in California); Hines v. Secretary of Dept. of Health and Human Servs., 940 F.2d 1518, 1526 (Fed. Cir. 1991) (taking judicial notice of the incubation period of measles); Dunn v. White, 880 F.2d 1188, 1195 (10th Cir. 1989) (holding that the district court properly took judicial notice of the seriousness of a disease in ruling on a motion to dismiss); Richardson v. Ribicoff, 205 F. Supp. 802, 805-06 (E.D.S.C. 1962) (noting that it is common knowledge that pain is one of the expected symptoms of arthritis).